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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/011,940 03/03/99 NAUCK

M 864861USWD

EXAMINER

HM22/0909

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ART UNIT

PAPER NUMBER

1654

DATE MAILED:

09/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File
copy

Office Action Summary

Application No.
09/011,940

Applicant(s)

Nauck et al.

Examiner

Bennett Celsa

Group Art Unit

1654



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, and 17-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1, 2, and 17-31 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-2 and 17-31 are currently pending.

The current application was filed under 35 USC 371 and is thereby subject to lack of unity rules.

LACK OF UNITY (Restriction & Election of Species)

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Accordingly, election of one (1) of the following groups is required:

Group I, claim(s) 1-2 and 17-25, drawn to a method for alimentary nutrition.

Group II, claim(s) 26-31 drawn to a composition comprising source of nutrients and insulinotropic peptide.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the "special technical feature" e.g. a composition comprising a CHO nutrient source and insulinotropic peptide, fails to define a contribution over the prior art since such compositions are available in the prior art. See E.g. Chen et al., U.S. Pat. No. 5,512,549 at col. 15-16 (Example 8) teaching glucose and insulinotropic peptide administered enterally, separately, or in combination; and Habener, U.S. Pat. No. 5,118,666 at bottom of col. 7 to top of col. 8 teaching compositions comprising insulinotropic peptides and several different sources of indirect/direct CHO nutrition.

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ELECTION OF SPECIES (upon election of Group I or II above)

This application contains claims directed to:

- a. CHO nutrient source; and
- b. inulinotropic peptide(s)

The above generic categories a. and b. encompass diverse compounds which include (but are not limited to) peptides comprised of different types of amino acids (e.g. L v. D amino acids), different amino acid content; different amino acid length which result in peptides which are structurally different and possess different conformation and would be expected to possess different physicochemical properties and/or be capable of separate manufacture (e.g. synthetic v. Recombinant) and/or use and result in different and burdensome searches including different classification searches and different bibliographic searches and different compound searches involving different programs as to necessitate different and/or separate burdensome searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species e.g.

- a. single CHO nutrient source (e.g. glucose etc.); AND
- b. single insulinotropic peptide (e.g. GLP-1 etc.)

which may be selected from either the specification and/or claims, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 26 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703)308-4028.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa

Bennett Celsa

September 3, 1999

**BENNETT CELSA
PATENT EXAMINER**